

### REMARKS

Reconsideration is courteously requested.

The abstract has been amended for the sake of brevity. The amended abstract generally conforms to that of Applicant's U.S. Pat. No. 6,719,709, i.e., application serial no. 09/943,975, the application from which the instant application depends.

At page 4, ¶9 of the DETAILED ACTION, joint inventor/ownership issues are raised in connection to prior art under 35 U.S.C. §103(a), more particularly, the applicability of §103(c) and §102(e), (f), or (g). The claimed subject matter of the instant application was commonly owned at the time any inventions covered therein were made.

#### **Engel et al.: Claims 30 & 34**

Engel et al. generally disclose an incontinence treatment device, more particularly, a user actuated valved catheter, i.e., an "on/off" switch for a catheter. A proximal valve is hydraulically actuated so as to permit urine ingress into and through a catheter lumen (FIG. 5): "...when the valve is open, [its design features] lead to no reduction the drainage lumen of the catheter so that an adequate urinary stream is assured" (3:28-30, see generally 3:16-36).

In contradistinction to the assessment at page 3 of the Action, Applicant's requirement of sequentially and incrementally returning portions of the prostatic urethra to an unsupported

condition during a bladder voiding event (claim 30), and/or manipulating a portion of said indwelling device so as to permit a prostate to physiologically act upon a prostatic responsive segment of said indwelling device (claim 34) are absent from Engel et al. As a matter of fact, such notions fly in the face of Engel et al. wherein lumen patency is critical to the functionality of a catheter, especially a valved catheter.

As best seen with reference to FIGS. 1 & 9, Engel et al. disclose a deployment tool 43 which is intended for partial insertion into a distal device end such that a free end 50b of a longitudinally shiftable rigid nucleus 50 "passes over the joint between parts 1 and 2 (shown as a dotted lines in FIG. 9) so that the joint is stabilized and the small pipes 17, 18 are protected from bending when the catheter is inserted" (13: 27-32). This device is not intended to aid lumen patency, nor is it possible to do so, especially in the prostatic urethra (see FIGS. 9 & 6: free end 50b is distal of balloon 11, and thus generally resides in the penile urethra). As Engel et al. do not disclose or fairly suggest one or more steps of the method of claims 30 & 34, these claims, and those depending therefrom, namely, claims 31-33 and 35-42, are in condition for allowance.

**Engel et al. & McRae: Claims 31-33 & 35-42**

McRae is generally directed to an apparatus and method for testing bladder pressure. A catheter equipped with a pressure

transducer is received within a penile urethra; a penile cuff is thereafter adjusted so as to constrict the penis and thereby prohibit urine discharge; attempted urination proceeds while pressure as a function of time is recorded; and, thereafter, the cuff is released, and urine discharged, with the rate and mass thereof determined/recorded. It is alleged that "the transient flowrate waveform generated at the time of pressure release from the cuff differentiates a proximal obstruction as from the prostate from a distal obstruction such as stenosis of the meatus" (6:8-11).

As neither Engel et al. nor McRae teach or otherwise disclose a sequential and incremental urodynamic assessment, Applicant's claimed subject matter is patentably distinct thereover. Furthermore, it is respectfully submitted that the relied upon combination is improper, there being no nexus between a valved indwelling catheter, and a bladder pressure assessment methodology, i.e., there can be no suggestion or motivation to combine such disparate teachings.

Finally, in connection to the allegations at page 5, ¶12 of the Action, Engel et al.'s "circular bulges or ribs 30" hardly satisfy Applicant's casting or casting related limitation of claims 33, 37, and 38. In contradistinction to Applicant's casting (see generally FIGS. 7-9, and pp. 31-36 of the application as filed), Engel et al. include a surface feature for the balloon, i.e., "change the surface of the balloon," as retaining means to prevent

dislocation of the indwelling device. As the features of Applicant's claims 33, 37 and 38 are absent from Engel et al., as well as McRae, these claims are patentably distinct therefrom.

**New Claims: 43-46**

Of the newly added claims, claim 43 is the sole independent claim. The newly added claims are generally directed to a lower urinary tract diagnostic method characterized by providing a diagnostic assembly comprising an elongate support member reversibly receivable within an elongate body, wherein the elongate body includes a physiologically responsive flexible wall segment for traversing a prostatic urethra (see e.g., claim 31 of Applicant's U.S. Pat. No. 6,719,709). As discussed in connection to claims 30 & 34, as the Engel et al. device lacks a combination of such features, the recited method of claim 43, and therefore those methods of the dependent claims, is patentably distinct from any disclosed or fairly contemplated Engel et al. method.

CONCLUSION

For the reasons above, it is respectfully submitted that the subject case is in condition for allowance. Early reconsideration and favorable action are solicited.

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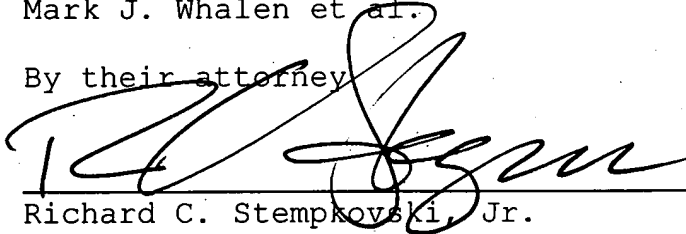
Respectfully submitted,

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By their attorney

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